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VIA E-FILING AND HAND DELIVERY

The Honorable Jennifer L. Hall
J. Caleb Boggs Federal Building
844 N. King Street
Unit 17, Room 6312
Wilmington, DE 19801-3555

Re: *Taiho Pharmaceutical Co., Ltd., et al. v. MSN Laboratories Private Ltd., et al.*
C.A. No. 21-CV-838-JLH (CONSOLIDATED)

Dear Judge Hall,

We are counsel for plaintiffs Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. in the action captioned above (the “838 Action”). Taiho respectfully requests the entry of a scheduling order for the 838 Action through trial. Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. dispute that a scheduling order should be entered in this matter at this time. The parties write to respectfully request resolution of this dispute.

Plaintiff Taiho’s Position:

Taiho and MSN are parties both to the 838 Action (captioned above) and to C.A. Nos. 19-2309, 19-2321, 19-2342, and 19-2368 (the “Polymorph Actions”), all pending before this Court. The 838 Action and the Polymorph Actions involve unrelated patents. No issue of fact or law to be resolved in the 838 Action will be affected by any issue in the Polymorph Actions. In late 2023 the parties were simultaneously litigating the 838 Action while preparing for trial in the Polymorph Actions. Fact discovery in the 838 Action concluded in January 2024, and MSN stipulated to infringement of the two patents at issue. D.I. 99. Pursuant to the then-existing case schedule, the 838 Action would have been ready for trial within five (5) months’ time. D.I. 68.

For efficiency purposes, in December 2023 the parties requested an extension of time in the 838 Action until trial in the Polymorph Actions concluded. Pursuant to a Stipulation and Order to Extend Time (838 Action, D.I. No. 102, the “Order”), the dates previously scheduled by the Court in the 838

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Action¹ were vacated and no schedule has since been entered. As the Order states, the stipulation resulted from the parties' agreement that "for efficiency purposes, the deadlines in this action [*i.e.*, the 838 Action] should be stayed while the parties prepare for and proceed to trial in the Polymorph Actions." D.I. 102 at 1.²

Trial in the Polymorph Actions concluded on April 9, 2024. At the Court's request after trial, the parties briefed an issue of claim construction and the final briefs were submitted on May 9, 2024. No further events have taken place in the Polymorph Actions. Thus, Taiho sought agreement from MSN's counsel concerning the entry of a scheduling order for the Remaining Events, but MSN has taken the position that it is "premature" to confer on this matter. MSN's sole articulated basis for this position is that the Order states that the parties are to meet and confer on a schedule for Remaining Events after post-trial briefing has been completed (D.I. 102 at 2), and no non-claim construction, post-trial briefs have been filed. But as noted above, the sole *reason* that the parties stipulated to an extension of time in the 838 Action was for the purpose of preparing for and proceeding to trial in the Polymorph Actions. With the trial concluded, the basis for the stipulated extension of time in the 838 Action no longer exists. Moreover, it was understood at the time of the stipulation that post-trial briefing likely would be completed a matter of weeks following trial.

Further, there is no independent justification or legal basis to extend the Remaining Events indefinitely into the future, which would effectively stay the 838 Action, because none of the factors favoring granting a stay exist in this case. *See UCB, Inc. v. Hetero USA Inc.*, 277 F. Supp. 3d 687, 690 (D. Del. 2017) (stating that the three factors courts in this district rely upon in determining whether a stay is appropriate are: (1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party). The outcome of the Polymorph Actions will have no effect on the 838 Action and it will not simplify any issues presented in the 838 Action. On the contrary, the 838 Action, in which MSN has stipulated to infringement, prevents MSN from launching a potential generic drug until well after the patents at issue in the Polymorph Actions expire. Further, since discovery in the 838 Action is complete, essentially the only events remaining are expert discovery, pretrial filings, and trial. Taiho's claims against MSN for infringing the patents in the 838 Action have been pending since February 2020 – almost five years ago. While MSN states that Taiho's proposal is prejudicial to MSN, it identifies no such prejudice. In contrast, keeping the 838 Action in limbo, as MSN suggests, serves only to prejudice Taiho, whose case preparation is growing stale and the availability of whose witnesses is becoming more fraught.

¹ 838 Action, D.I. 27, and as amended thereafter (D.I. 27, D.I. 35, D.I. 47, D.I. 68, and D.I. 102).

² As set forth in the Order, the "Remaining Events" that require scheduling in the 838 Action are: (i) Defendants' Final Election of Asserted Prior Art; (ii) Plaintiffs' Final Election of Asserted Claims; (iii) Opening Expert Reports; (iv) Rebuttal Expert Reports; (v) Reply Expert Reports; (vi) Completion of Expert Depositions; (vii) Daubert Motions; (viii) Pretrial Conference; and (ix) Trial. D.I. 102 at 2.

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The reason for the stipulated extension of time in the 838 Action has expired and there is no other basis to stay the 838 Action. Accordingly, Taiho respectfully seeks entry of a schedule for the Remaining Events in the 838 Action as follows:

Event	Proposed Date
Defendants' Final Election of Asserted Prior Art	January 31, 2025
Plaintiffs' Final Election of Asserted Claims	February 7, 2025
Opening Expert Reports	February 21, 2025
Rebuttal Expert Reports	March 21, 2025
Reply Expert Reports	April 18, 2025
Completion of Expert Depositions	June 20, 2025
Deadline to file Daubert Motions	July 18, 2025
Pretrial Conference	TBD based on Court's schedule
Trial	TBD based on Court's schedule

The intervals between these events closely follow those the Court previously ordered for them. D.I. 27; D.I. 68. At no time has the Court ever ordered a stay of the 838 Action until a final judgment was entered or an appeal was taken in the related cases.

Defendant MSN's Position:

MSN respectfully requests that the Court deny Taiho's invitation to enter a schedule for the Remaining Events in the 838 action because such request is premature. On November 8, 2023, Taiho and MSN³ attended a hearing before Judge Connolly. *See* Attached Exhibit. The subject of the hearing was Defendants' motion under Fed. R. Civ. P 54(b) to obtain a final judgment on the only patent that had been adjudicated by Chief Judge Connolly at that time—U.S. Patent No. RE46,284 ("the '284 patent")—so that the Defendants could appeal the Court's judgment to the Federal Circuit. Chief Judge Connolly engaged the parties in a conversation on how to adjudicate the remaining patents—the polymorph patents and the severe renal impairment ("SRI") patents—in the case.

³ MSN's former counsel attended the November 8, 2023 hearing. MSN's present counsel entered appearances in this action in March 2024.

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In the back-and-forth with Chief Judge Connolly, Taiho's counsel suggested that Defendants' Rule 54(b) motion be denied in order for the Court move ahead with trial in the Polymorph Actions so that the Parties would then have appealable final judgments in both the '284 patent action and the Polymorph Actions. *See* Attached Exhibit at 6:7-7:3. Taiho's counsel then suggested that the Court needn't worry about the SRI patents if "we move forward and get the polymorph trial done." *See id.* at 7:4-20. Rather, Taiho's counsel suggested that the '284 patent and the Polymorph Actions would be fully decided and judgments entered before moving forward with the SRI patents. *See id.*

At that hearing, Chief Judge Connolly also informed the Parties that these cases would be transferred to your Honor, and that the Polymorph Actions would be tried as soon as this Court "can get it on the calendar." *See id.* at 18:7-16. And, "at that point, you all agree that the '284 tranche and the polymorph tranche can go on appeal to the Federal Circuit [while] the SRI cases are all severed and treated differently an are put on the back burner." *Id.* Taiho's counsel agreed with that approach. *Id.* at 19:3-8.

It is clear from the November 8, 2023 hearing that the spirit of the agreement between the Court and the Parties was that the Polymorph Actions would be adjudicated first so that the '284 patent and Polymorph Actions would be fully decided and ready for appeal, with the foreseeable consequence that the SRI patents would be put on the "back burner." *Id.* at 18:7-16. And based on this agreement, the Parties stipulated that the deadlines in actions involving the SRI patents would be stayed until "fifteen (15) days of the parties filing the final post-trial brief in the Polymorph Actions." *See* D.I. 102.⁴ As Taiho notes, trial in the Polymorph Actions was completed on April 9, 2024, after which the Parties engaged in claim construction briefing—not post-trial briefing—that was completed on May 9, 2024. Taiho did not communicate with MSN until December 13, 2024, at which time—to MSN's surprise—Taiho sent an email seeking to restart the SRI patent action and proposed an accelerated expert discovery schedule without having any idea when trial on the SRI patents would be scheduled.

Taiho's proposal is prejudicial to MSN, which is seeking entry of final judgement on the '284 patent and Polymorph Actions so that those issues can be immediately appealed prior to moving forward with the SRI patent, which is what the Parties contemplated before these cases were transferred to Your Honor. Further, the 30-month stay of FDA-approval for MSN's ANDA Product has now passed, and MSN's ANDA has received final approval from FDA.

On the other hand, Taiho is not prejudiced by abiding by the Parties' stipulation and waiting until final post-trial briefing is completed in the Polymorph Actions before moving forward with the SRI patents. That is consistent with the spirit of the what the parties agreed to with Judge Connolly in the November 8, 2023 hearing, and is consistent with Judge Connolly's statement that this is "the most judicially efficient and fair way." What's more, the SRI patents do not expire until 2037. Judge Connolly already adjudicated the '284 patent in Taiho's favor, and the '284 patent does not expire until 2029. Once

⁴ As a result of the November 8, 2023 conference, and to further facilitate the appeal of the '284 patent and Polymorph Actions without a subsequent Rule 54(b) motion, MSN and Taiho entered into a stipulation moving the '399 (SRI) patent from Case No. 19-2342 and into the consolidated 838 Action on the SRI patents.

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the Court enters judgment on the Polymorph Actions, both the '284 patent and Polymorph Actions can be appealed. This approach would also avoid burdening the Court and the Parties with another action in this case before the Court has had the opportunity to receive the parties' post-trial briefing in the Polymorph Actions.

In the alternative, if the Court decides that the 838 Action should move forward now, MSN respectfully requests that the Court set a trial date to hear the SRI patents in Q1/2026 or after, from which the Parties can work backwards to reach an agreed upon schedule.

* * *

The parties thank the Court for its time in considering this matter.

Respectfully submitted,

/s/ Ethan H. Townsend

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EHT/clm

cc: All Counsel of Record (via CM/ECF)